IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Seng H. Cheng et al.	Group Art Unit: 1632
Application No.: 10/758,773	
Filed: January 16, 2004	Examiner: Shin-Lin CHEN
For: COMBINATION ENZYME REPLACEMENT, GENE THERAPY AND SMALL MOLECULE THERAPY FOR LYSOSOMAL STORAGE DISEASES	Confirmation No.: 6298

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

This paper is filed in reply to the Office Action mailed April 10, 2006. The period for response has been extended by two months to August 6, 2006 by the accompanying Petition for Extension of Time and fee to be charged to Deposit Account No. 06-0916.

The Examiner required restriction under 35 U.S.C. § 121 among twelve groups of claims:

Group I Claims 1-9, 13-18, and 20-21, drawn to a method of treating a subject having a lysosomal disease, such as Fabry disease, comprising administering a gene therapy vector [under the control of a tissue specific regulatory element] and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-galactosidase;

Group II Claims 1, 3, 4, 7-9 and 13-21, drawn to a method of treating a subject having a lysosomal disease, such as Fabry disease, comprising administering a gene therapy vector [under the control of a tissue specific regulatory element] and a small molecule capable of treating a lysosomal storage disease;

Group III Claims 1-9 and 13-21, drawn to a method of treating a subject having a lysosomal disease, such as Fabry disease, comprising administering a gene therapy vector [under the control of a tissue specific regulatory element], an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-galactosidase, and a small molecule capable of treating a lysosomal storage disease;

Group IV Claims 1-6, 10-18, and 22, drawn to a method of treating a subject having a lysosomal disease, such as Pompe disease, comprising administering a gene therapy vector [under the control of a tissue specific regulatory element] and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-glucosidase;

Group V Claims 1-6, 10-19, and 22, drawn to a method of treating a subject having a lysosomal disease, such as Pompe disease, comprising administering a gene therapy vector [under the control of a tissue specific regulatory element] and a small molecule capable of treating a lysosomal storage disease;

Group VI Claims 1-6, 10-19, and 22, drawn to a method of treating a subject having a lysosomal disease, such as Pompe disease, comprising administering a gene therapy vector [under the control of a tissue specific regulatory element], an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-glucosidase, and a small molecule capable of treating a lysosomal storage disease;

Group VII Claims 23, 24, 26-32, and 34, drawn to a composition for treating a lysosomal storage disease, such as Fabry disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-galactosidase, under the control of a tissue specific regulatory element and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-galactosidase;

Group VIII Claims 23, 24, 26, 27, and 29-34, drawn to a composition for treating a lysosomal storage disease, such as Fabry disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-galactosidase, under the control of a tissue specific regulatory element and a small molecule capable of treating a lysosomal storage disease;

Group IX Claims 23, 24, and 26-34, drawn to a composition for treating a lysosomal storage disease, such as Fabry disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-galactosidase, under the control of a tissue specific regulatory element and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-galactosidase, and a small molecule capable of treating a lysosomal storage disease;

Group X Claims 23, 25-32, and 35, drawn to a composition for treating a lysosomal storage disease, such as Pompe disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-glucosidase, under the control of a tissue specific regulatory element and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-glucosidase;

Group XI Claims 23, 25-27, 29-33, and 35, drawn to a composition for treating a lysosomal storage disease, such as Pompe disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-glucosidase, under the control of a tissue specific regulatory element and a small molecule capable of treating a lysosomal storage disease;

Group XII Claims 23, 25-33, and 35, drawn to a composition for treating a lysosomal storage disease, such as Pompe disease, comprising a gene therapy vector encoding a lysosomal hydrolase, such as alpha-glucosidase, under the control of a tissue specific regulatory element and an exogenously produced natural or recombinant lysosomal hydrolase, such as alpha-glucosidase, and a small molecule capable of treating a lysosomal storage disease,

The restriction of certain groups is subject to non-allowance of linking claims. Multiple alternative linked groups are provided. In particular, claims 1, 3, 4, 13-18, and 20-21 link inventions I-VI. Claims 7-9 link inventions I-III. Claims 2, 5 and 6 link inventions I and III-VI. Claim 19 links inventions II-III, V and VI. Claims 20 and 21 link inventions 1-III. Claims 10-12 and 22 link inventions IV-VI.

Applicants provisionally elect to prosecute Group I, subject to the following:

- in the event of allowability of any of linking claims 1, 3, 4, 13-18, and 20-21, Applicants elect to prosecute Groups I-VI;
- in the event of allowability of any of linking claims 2, 5, and 6, Applicants elect to prosecute Groups I and III-VI; and

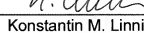
- in the event of allowability of any of linking claims 7-9 and 20-21, Applicants elect to prosecute Groups I-III.

Please grant any extensions of time required to enter this response and charge the fee of $1020.00 and any additional required fees to Deposit Account No. 06-0916. The Examiner is welcome to call the undersigned with any questions.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: August 3, 2006

By: 

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